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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,275	08/30/2001	John David Bentley	50179-081	9040

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,275	BENTLEY ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1 page* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-33 are under consideration by the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The only steps set forth in claims 1-20 are manipulation of data which is non-statutory. See MPEP 2106.

Claim Rejections - 35 USC § 112

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

The specification discloses crystallizing a truncated portion of the IGF-1R. The structure of this truncated, minimally glycosylated fragment was determined to 2.6 angstroms by X-ray

crystallography. The claims are directed to designing a compound where the compound designed has a particular property. The specification exemplifies no modeling of any molecule nor does the specification disclose any compounds meeting the structural and functional limitations required by the claims. As written, claims 1-20 recite the single step of assessing the stereochemical complementarity between a compound and a recited molecule. Note that the claims do not recite that a particular level of stereochemical complementarity is required and the claims include no design steps. In addition, the specification provides no guidance as to the stereochemical complementarity (by degree or to which particular portion(s) of the molecule) required to get a molecule with the recited functional limitation. For example, what degree of stereochemical complementarity and to which amino acids does the compound need to have to have a K_I of less than 10^{-6} M? (See claim 16.) It is unknown and cannot be predicted from the information presented in the specification.

In particular, claim 1 requires that the compound bind to any molecule of the insulin receptor family (see specification for the large number of receptors encompassed) and modulate any activity mediated by the molecule (particular activity of the molecule unknown or unspecified by the claim). What activity? Which receptor?

In particular, claim 13 requires designing a molecule which increases an activity mediated by a molecule of the receptor family. What activity? Which receptor?

In particular, claim 14 requires designing a molecule which decreases an activity mediated by a molecule of the receptor family. What activity? Which receptor?

Claims 21-28 are directed to a computer-assisted method for identifying potential compounds. The steps include inputting the atomic coordinates of Figure 1 or a subset thereof,

generating atomic coordinates for a structure that possesses stereochemical complementarity, generating a criteria data set, comparing the criteria data set to a database, and selecting structurally similar chemical structures. The comments regarding stereochemical complementarity as set forth above with respect to claims 1-20 apply here as well as comments concerning the biological activity. In addition, the specification provides no guidance on what a criteria data set must include or how it is generated. The specification provides no guidance on how to compare this data set to a computer database. The specification provides no guidelines or criteria by which selection must be made. The specification does not identify any database known to those of ordinary skill in the art that could be used in the method as claimed.

Claims 29-33 are directed to methods of screening a compound by identifying a compound as set forth in claim 1 and testing the compound. All of the comments concerning claims 1-20 would apply to these claims.

Undue experimentation would be required to practice the claimed invention as the specification provides no examples and no guidance as how to design molecules resulting in the required properties and the breadth of the claims is very large. Disclosure of using well known computer programs for modeling cannot be considered guidance for designing or selecting compounds with particular properties. (See at least pages 45-46.) This is an invitation to experiment. Note that the claims encompass using unspecified subsets of with no atomic structure known (see at least claim 1) or an unspecified subset of atomic coordinates (see at least claim 21). At the very least, one using these programs would have to make decisions with respect to choosing the particular amino acids to consider for assessing stereochemical complementarity, determining what levels of stereochemical complementarity are meaningful,

and exercising judgment with respect to which compounds to choose for evaluation (for those claims requiring testing of activity). This is not routine experimentation.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "assessing the stereochemical complementarity between the compound and receptor site of the molecule." While the claim goes on to delineate the identity of the receptor site, it is not known what delimits a receptor site.

Claim 1 recites "substantially as shown" and "forms an equivalent." It is unknown what degree of similarity is required to meet these limitations. It is unknown what three dimensional structures are encompassed by the claims.

Claim 4 refers to "at the surface of the receptor site lining the groove, as depicted in Figure 2." Figure 2 does not refer to a groove. As such, it is unclear what part of the molecule in Figure 2 is being referred to and what the claim encompasses. It is unclear if particular structural coordinates or some three dimensional structure is a limitation of the claim.

In addition, claim 3 discusses the end product (the product designed or selected) without clearly modifying the method steps to result in the desired product. That is, it does not clearly further limit the active steps of claim 1. See also at least claims 4-18, 22, and 25.

Claim 4 recites "to make close contact." It is unknown what level of contact is required to meet this limitation.

At least claims 5-6 recite "such that it can interact." It is not known what is considered to meet this limitation. What degree of interaction is required?

Claims 16-18 recite a K_1. This appears to be a typographical error for K_I.

Claims 19-20 identify the receptor. It is unclear what part of claim 1 this is supposed to further limit. See also claims 27-28 with respect to claim 21.

Claim 21 recites "which are structurally similar to a portion." It is unknown what degree of similarity is required to meet this limitation. It is unknown how much of the criteria data set constitutes "a portion."

Claim Rejections - 35 USC § 103

Claims 1-20 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendry et al. (U.S. Patent No. 5,705,335).

Hendry et al. teaches assessing stereochemical complementarity of a compound to a receptor, obtaining the compound, and assessing it for biological activity. These steps are the only steps required by the claims.

The difference between the prior art and the claimed invention is the recited three dimensional structure information. This information is descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change in the processing steps and are thus nonfunctional descriptive material. The claimed invention uses known software to solve a known problem in a conventional manner. The instant specification acknowledges known prior art computer modeling techniques. Neither the specification nor the claims set forth any special, non-obvious modifications to the known, conventional software and

method steps. A method of using a known comparator (e.g. computer modeling techniques known in the prior art to Hendry) for its known purpose to compare data sets does not become nonobvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. See *In re Gulack*, 703 F. 2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106. Applicant is also directed to the Trilateral Project WM4 Report on Comparative Study on Protein 3-dimensional (3-D) Structure Related Claims at http://www.uspto.gov/web/tws/wm4/wm4_3d_report.htm.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
February 5, 2003